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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

18M2/1016

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| APPLICATION NO. | FILING DATE | TOTAL CLAIMS | EXAMINER AND GROUP ART UNIT | DATE MAILED |
|-----------------|-------------|--------------|-----------------------------|---------------|
| 08/238,080 | 05/03/94 | 040 | REES, D | 1807 10/16/97 |

TITLE OF INVENTION COLLINS, MARK L.

TARGET AND BACKGROUND CAPTURE METHODS WITH AMPLIFICATION FOR AFFINITY ASSAYS

| ATTY'S DOCKET NO. | CLASS-SUBCLASS | BATCH NO. | APPLN. TYPE | SMALL ENTITY | FEE DUE | DATE DUE |
|-------------------|----------------|-----------|-------------|--------------|-----------|----------|
| 2583511 | 435-006.000 | 118 | UTILITY | NO | \$1320.00 | 01/16/98 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.
If the SMALL ENTITY is shown as yes, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "6b" of Part B should be completed.

III. All communications regarding this application must give application number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Patents Issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

Notice of Allowability

Application No.

08/238,080

Applicant(s)

Collins et al.

Examiner

Dianne Rees

Group Art Unit

1807



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to 7/10/97, 7/14/97

☒ The allowed claim(s) is/are 25-50 and 53-66

☐ The drawings filed on _____ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 22

☐ including changes required by the proposed drawing correction filed on _____, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

Art Unit:

DETAILED ACTION

1. The following is an examiner's statement of reasons for allowance:

The claims are drawn to methods of PCR amplification wherein the target is first separated from the sample by using a support that binds to the target polynucleotide and then amplified. In further embodiments of the invention a probe is contacted to a target and the target probe complexes then contacted to the support which binds to the probe and the support and complex are separated from the medium, The probe target complex is then leased into a second medium and substantially separated from the support and the target is subsequently amplified..The instant application has priority to 10/23/86

The closest prior art is Vary et al and Henson et al. Vary et al teaches a method for amplifying and detecting a target polynucleotide in a sample comprising amplifying the target polynucleotide by primer extension, immobilizing the amplified polynucleotide on a support , separating the amplified polynucleotide and detecting said polynucleotide. Vary et al does not teach binding a target polynucleotide to the support prior to amplification and does not teach retrievable supports. Henson et a teaches general methods of isolating a target sequence of interest from a sample by immobilization onto a solid support and that the order of reaction

Art Unit:


between a single stranded nucleic acid and a probe and a support may be varied according to experimental needs. However, the art at the time of filing did not recognize that the efficiency of PCR amplification would decrease due to the presence of contaminants in a sample and therefore provided no motivation to purify a target sample from a heterogenous sample of nucleic acids prior to amplification. Having not recognized the problem, applicant's solution therefore, while utilizing routine methodology to modify PCR amplification techniques, would not have been obvious at the time that the invention was made. The Declaration of Dr. David Pershing, further supports this conclusion as providing further evidence concerning the skill of the art at the time of filing, attesting that one of skill in the art would likely stay away from combining a hybridization capture method with a PCR method since one would not be motivated to provide a method with the potential to lose target nucleic acids prior to amplification.

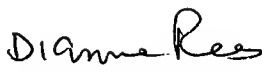
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit:

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dianne Rees whose telephone number is (703) 308-6565.

08238080


W. GARY JONES
SUPERVISORY PATENT EXAMINER
GROUP 1800
10/14/97


Dianne Rees
October 13, 1997
10/13/97